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Feasibility randomized-controlled trial of online Acceptance and Commitment
Therapy for patients with complex chronic pain in the United Kingdom

Running Head: ACT Online UK Feasibility Trial

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Disclosures: Whitney Scott, Beth Guildford, and Lance McCracken deliver ACT-based treatment for pain within the UK's National Health Service, and they provide training in ACT to students. Lance McCracken is a section editor at the European Journal of Pain. The authors declare no further conflicts of interest.

Significance: This is the first study supporting the feasibility of online Acceptance and Commitment Therapy for chronic pain in the United Kingdom and a larger efficacy trial. Refinements to treatment delivery, particularly to better engage employed patients, may improve treatment completion and outcomes.

Key Words: Chronic pain; Acceptance and Commitment Therapy; Internet delivery

Abstract

Background: Acceptance and Commitment Therapy (ACT) has growing support for chronic pain. However, more accessible treatment delivery is needed. This study evaluated the feasibility of online ACT for patients with complex chronic pain in the United Kingdom to determine whether a larger trial is justified. **Methods:** Participants with chronic pain and clinically-meaningful disability and distress were randomly assigned to ACT online plus specialty medical pain management, or specialty medical management alone. Participants completed questionnaires at baseline, and three- and nine-months post-randomisation. Primary feasibility outcomes included recruitment, retention, and treatment completion rates. Secondary outcomes were between-groups effects on treatment outcomes and psychological flexibility.

Results: Of 139 potential participants, 63 were eligible and randomized (45% recruitment rate). Retention rates were 76-78% for follow-up assessments. Sixty-one percent of ACT online participants completed treatment. ACT online was less often completed by employed (44%) compared to unemployed (80%) participants. Fifty-six percent of ACT online participants rated themselves as 'much improved' or better on a global impression of change rating, compared to only 20 percent of control participants. Three-month effects favouring ACT online were small for functioning, medication and healthcare use, committed action and decentering, medium for mood, and large for acceptance. Small to medium effects were maintained for functioning, healthcare use, and committed action at nine-months. **Conclusions:** Online ACT for patients with chronic pain in the United Kingdom appears feasible to study in a larger efficacy trial. Some adjustments to treatment and trial procedures are warranted, particularly to enhance engagement among employed participants.

Key Words: Chronic pain; Acceptance and Commitment Therapy; Internet delivery

Introduction

Evidence supports the efficacy of cognitive-behavioural therapy (CBT) for chronic pain (Williams et al., 2012). Acceptance and Commitment Therapy (ACT) is a newer form of CBT with growing evidence. Pooled effects show acceptance-based treatments are associated with small to medium improvements in disability and mood compared to inactive controls, which is comparable to traditional CBT (Veehof et al., 2016). ACT achieves better reduction in pain-related disability immediately post-treatment compared to active treatments, including relaxation (Kemani et al., 2015) and expressive writing (Trompetter et al., 2014).

Barriers remain to accessing psychological treatments such as ACT for chronic pain. There is limited availability of ACT-based treatments outside of specialized pain management centres (PMCs), and these are resource-intensive (Scott and McCracken 2015b). These treatments are often group-based, which can be unsuitable for some people. Transportation, employment, or caregiving responsibilities represent other potential barriers to access.

Given world-wide problems with treatment access and cost, the Internet may provide a solution for delivering psychotherapy (Andersson 2016). Across a range of health problems, evidence shows comparable outcomes using therapist-assisted online formats compared to face-to-face (Andersson et al., 2014). Emerging evidence supports the efficacy of online psychotherapy for chronic pain (Dear et al., 2015; Eccleston et al., 2012).

Few studies have examined Internet-delivered ACT for chronic pain. One Swedish RCT (N=76) found that Internet ACT produced small to moderate improvements for mood and pain interference compared to an online discussion forum (Buhrman et al., 2013). One Dutch RCT (N=238) found that participants who

received guided online ACT showed greater improvements in pain, disability, and depression compared to expressive writing and waitlist conditions (Trompetter et al., 2014). A German study showed participants who received guided online ACT had moderate improvements in pain interference compared to a waitlist control (Lin et al., 2017).

The feasibility of online ACT for chronic pain in the United Kingdom has not been evaluated. Appreciating feasibility is important because there are challenges in online delivery of treatment, including a need for skills to engage with the Internet, and for forming a therapeutic alliance with limited human interaction (Christensen et al., 2009; Eccleston et al., 2012). Moreover, only one trial of online ACT has recruited from a pain clinic (Buhrman et al., 2013). Community-recruited samples are self-selected, may have low levels of distress and disability, and more motivation (Eccleston et al., 2012). Therefore, it is important to examine online ACT in varying contexts, such as in other pain clinics and for people presenting with greater complexity, particularly more severe pain-related disability and distress.

This study examined the feasibility of online ACT for patients with chronic pain in the United Kingdom to determine whether a larger RCT is warranted. Participants were randomly assigned to ACT online plus consultant-lead medical management in a speciality chronic pain clinic, or specialty medical pain management alone. We hypothesized that ACT online would be acceptable to patients in this context and that a larger trial would be feasible.

Methods

Trial Design

The trial was registered prior to recruitment and a summary protocol is available online (ISRCTN81739991). This study was a parallel-groups, randomized-controlled, feasibility trial. Following baseline assessment, participants were randomly assigned (1:1 ratio) to ACT online plus specialty medical treatment for pain, or specialty medical treatment only, using computer-generated random numbers (www.random.org). Sealed, sequentially numbered opaque envelopes were used to conceal the sequence, which had been produced by an independent researcher who had no other involvement in the trial. The lead author (WS) enrolled participants and informed them of their treatment condition subsequent to another researcher (AD) opening the envelope. Blinding of treatment assignment from therapists, participants, and researchers was not possible particularly due to the nature of the treatment.

Participants completed assessments at baseline, and three and nine months following randomization. Participants completed self-report questionnaires through Bristol Online Survey (<https://www.onlinesurveys.ac.uk>), a secure survey platform. The researcher who sent the questionnaire weblink was aware of participants' treatment assignment; however, all participants received a standardized email and subsequently completed questionnaires independently.

For feasibility studies, a formal sample size calculation is generally not warranted (Billingham et al., 2013). However, a sample of 30 to 36 participants per arm has been suggested based on the median sample size identified in a systematic review of feasibility studies (Billingham et al., 2013). Based on a predicted attrition rate of 20 percent, we initially aimed to recruit 90 participants to have approximately 70 participants (35 per arm) at follow-up. However, we did not achieve this recruitment within the timeframe of the study due, in part, to lack of resources for

recruitment. Despite this, and given the primary feasibility aims, the recruitment and retention achieved (63 participants at baseline, and 48/49 participants at follow-up) remains within sample size recommendations for feasibility trials (Julious 2005). Additionally, the number of participants at follow-up is above the inclusion criterion of 20 participants per arm from a previous Cochrane review of psychological treatments for pain (Williams et al., 2012). This study was approved by the National Research Ethics Service—London Central Research Ethics Committee (Reference: 14/L0/1936), and the Research and Development department at Guy's and St Thomas' Hospital National Health Service Foundation Trust (Reference: RJ115/N108). The study was conducted in accordance with the ethical standards in the 1964 Declaration of Helsinki and its later amendments.

Recruitment

Participants were recruited from the Pain Management Centre (PMC) at St. Thomas' Hospital in London between August 2015 and June 2016. The PMC is a specialty chronic pain clinic accepting referrals from primary and secondary care. The final follow-up assessment was completed in May 2017. Participants were informed of the study by their treating PMC clinician (consultant physician or nurse) during a routine outpatient visit. Inclusion criteria were: (a) adult outpatients (18 years or older), (b) chronic non-malignant pain of at least 3 months duration, and (c) clinically significant pain, pain-related disability, and distress as reflected by average pain intensity and interference scores over the last week of ≥ 4 on a 10-point numerical rating scale and a score of ≥ 3 on the PHQ-2 depression symptoms screen (Löwe et al., 2005). Exclusion criteria were (a) previous ACT or CBT for chronic pain, (b) current participation in another psychological treatment, (c) severe and poorly

controlled psychiatric disorder (e.g., schizophrenia, bipolar disorder) or other conditions expected to impair treatment engagement (e.g., cognitive impairment), (d) inability to complete study procedures online in English. A clinical psychologist conducted the eligibility screening. All participants provide written informed consent. A CONSORT diagram detailing recruitment, allocation, and retention is shown in Figure 1.

Participants

Table 1 shows baseline demographic data of the 63 participants. The majority of the sample was female (63.5%), with a mean age of 45.52 years (sd=13.98). The majority of the sample (55.6%) was working full- or part-time, while 39.7% were receiving some form of disability income. Lower back pain was the most frequent primary pain complaint (30.2%), followed by widespread pain (14.3%), pain in the lower limbs (12.7%), and pelvic pain (11.1%), or other (31.7%). Participants frequently (84.1%) reported pain in multiple sites. Participants experienced longstanding pain (median: 6.75 years; range: 0.75-47.50 years). Participants were experiencing clinically-meaningful levels of pain intensity, interference, and depression symptoms at baseline based on previously identified cut-off scores on the measures used to assess these variables (Manea et al., 2012; Zelman et al., 2003).

Treatments

ACT Online (Experimental Group)

Participants received the ACT online treatment within one to two weeks of being randomized to this condition. Exercises aimed to increase patients' awareness of the

long-term consequences of struggling to control pain, their willingness to experience pain when practical to do so, and their engagement in values-based activities (Dahl and Lundgren 2006; McCracken and Vowles 2014). Sessions were organised around key processes of psychological flexibility labelled as behaviour that is “open, aware, and engaged” (Hayes et al., 2011). Participants received ACT online in addition to medical treatment within a consultant-lead speciality pain management service (described below).

Online treatment sessions consisted of videos providing brief background and guiding participants through experiential exercises and metaphors. The videos ranged in length from 8 to 27 minutes (mean 17 minutes). The treatment was therapist supported. Treatment commenced with a 30 to 45 minute face-to-face or telephone session with the therapist aimed at fostering the therapeutic alliance, exploring the pain problem and current pain management strategies, explaining the treatment model, and setting preliminary goals. The therapist subsequently emailed the participant a secure weblink to access their online treatment sessions.

Participants received a standardized package of eight online sessions (Table S1), twice weekly for the first three weeks, and once weekly for the final two weeks. The therapist could augment this core treatment package with additional exercises depending on each participant’s progress. Treatment finished with a final face-to-face or telephone session to review progress, set longer-term goals, and plan for barriers. Participants were expected to complete the treatment within 10-12 weeks.

Following each session, participants responded to questions assessing their experiences in session. Each week, participants were also asked to rate three items assessing the extent to which their behaviour reflected the qualities of being “open, aware, and engaged”. The therapist provided individualized written feedback within

24-72 hours to any inputs from the participants. Feedback focussed on reinforcing session completions and on shaping and reinforcing psychological flexibility.

Therapists prompted participants with reminders to complete sessions as scheduled, and could request a brief telephone call to discuss engagement after several reminders. Therapists kept a log of completed and non-completed sessions, and any adverse events.

All therapists were working in the INPUT Pain Management Unit at St Thomas' Hospital, which provides pain management according to the ACT model. Therapists' experience levels were: Master's-level assistant psychologist with three months supervised experience providing ACT for pain (AD) and three doctoral-level clinical psychologists with one (WS), five (BG), and 20+ (LM) years' experience delivering ACT for pain. Treatment fidelity was facilitated through attendance at weekly clinical development meetings routine within INPUT Pain Management Unit, and through regular supervision meetings to discuss participants.

Speciality Pain Management Medical Treatment (Control Group)

Patients randomized to the control arm received consultant-led medical management of pain that is standard within the speciality chronic pain clinic from which participants were recruited. Treatments within this clinic primarily include oral medication management, mainly antidepressant or anticonvulsant medications, or interventional procedures, such as epidural, nerve root, or joint injections. Specialist pain consultants routinely use these treatments.

Assessment Procedures

During the baseline assessment, participants answered questions about their gender, age, ethnicity, living situation, education, work status, income, and pain duration and location.

Primary Feasibility Outcomes

Primary feasibility outcomes for the trial included: willingness to be randomized, recruitment and retention rates, ACT online treatment completion, treatment satisfaction, and data completeness. ACT online treatment completion was computed as the proportion of participants that received a complete treatment dose, defined a priori as completing at least 7 out of 10 treatment sessions.

At three-months, participants rated five items assessing their satisfaction with treatment, in light of recommendations that treatment satisfaction is a “crucial feature” to assess to RCTs of Internet-delivered psychotherapy for chronic pain (Eccleston et al., 2012). Treatment satisfaction items were adapted from a validated measure of treatment credibility (Deville and Borkovec 2000). Participants rated items from 0 (not at all) to 10 (completely). Additionally, ACT online participants rated five items assessing specific aspects their treatment experience: therapist contact, videos, writing about post-session reactions, and weekly diary ratings. ACT online participants also completed six open-ended questions asking which treatment components were most and least helpful, any negative effects experienced, and suggested improvements.

Secondary Outcomes

Patient Global Impression of Change scale (PGIC): Patients responded to one question regarding their perception of overall change during treatment using a rating

scale with options “very much improved,” “much improved,” “minimally improved,” “no change,” “minimally worse,” “much worse,” “very much worse” (Guy 1976). The PGIC has been extensively used in clinical trials for chronic pain (Farrar et al., 2001). Previous research indicates the single-item PGIC reflects treatment-related improvement in multiple domains of daily functioning and mood, in addition to changes in pain (Scott and McCracken 2015a).

Pain intensity and pain-related distress: Participants rated their average pain intensity and pain-related distress over the previous week on an 11-point numerical rating scale with the endpoints 0 (no pain) to 10 (extremely intense pain).

Brief Pain Inventory Interference Scale (BPI Interference): The BPI Interference Scale (Cleeland and Ryan 1994) is a seven-item self-report measure that assesses the extent to which pain interferes with general activity, walking, work outside and inside the home, sleep, mood, enjoyment of life, and relationships, each rated on a 0 (does not interfere) to 10 scale (completely interferes). The BPI is extensively used in chronic pain research, has strong psychometric properties and is recommended as an outcome in clinical trials of patients with chronic pain (Dworkin et al., 2005).

Work and Social Adjustment Scale (WSAS): The WSAS is a five-item measure that assesses the impact of a health condition on functioning in the following domains: work, home management, social leisure activities, private leisure activities, and relationships. Participants rated questions on a nine-point scale ranging from 0 (no impairment) to 8 (very severe impairment). The WSAS shows good reliability and

has been validated across a range of chronic health conditions (Cella et al., 2011; Mundt et al., 2002).

Patient Health Questionnaire (PHQ-9): The PHQ-9 (Kroenke et al., 2001) is a nine item measure of depression symptoms based on the DSM-IV criteria for depression. Participants rated each item on a four-point scale between 0 (not at all) and 3 (nearly every day). The PHQ-9 is sensitive to change, and has demonstrated reliability and validity as a measure of depression symptoms (Kroenke et al, 2001).

Healthcare and Medication Use: Participants reported on the number of GP, specialist, and accident and emergency visits in the preceding three-months (McCracken et al., 2013). Additionally, participants reported whether they were taking (yes/no) the following classes of medications: opioids, anticonvulsants, tricyclic antidepressants, selective serotonin reuptake inhibitors or serotonin-norepinephrine reuptake inhibitors, non-steroidal anti-inflammatory drugs, anxiolytics or muscle relaxants, and hypnotics or sleep medication. The number of medication classes were summed to create a medication use index (McCracken et al., 2005).

Chronic Pain Acceptance Questionnaire (CPAQ-8): The CPAQ-8 is a validated shorter version of the original CPAQ, which has been widely validated and used as a measure of chronic pain acceptance (Fish et al., 2010; McCracken et al., 2004). The CPAQ-8 includes two factors reflecting engagement in important activities with pain, and willingness to experience. Items are rated on a seven-point scale (0=never true, 6=always true). When summed, higher scores reflect greater acceptance.

Experiences Questionnaire (EQ): The EQ is a 12-item measure of decentering, which reflects the capacity to experience thoughts and feelings as transient events and not necessarily a matter of reality, a key ACT treatment process (Fresco et al., 2007). Patients were asked to rate statements on a scale from 1 (never) to 5 (all the time). Higher scores represent greater decentering. The EQ has been demonstrated to have good reliability and validity in a sample of patients with chronic pain (McCracken et al., 2014b).

Committed Action Questionnaire (CAQ-8): The CAQ-8 is a measure of committed action, which describes the degree to which individuals continue to flexibly pursue valued goals in the presence of challenges, a key treatment process of ACT (McCracken et al., 2014a; McCracken 2013). Data support the psychometric properties of the CAQ-8 in patients with chronic pain (McCracken et al., 2014a).

Feasibility Criteria

We planned to regard the treatment as feasible if we could (a) recruit 90 and retain 70 participants, (b) achieve a treatment completion rate of 70 percent, (c) achieve a rate of less than 10 percent of missing questionnaire data, and (d) surpass a participant satisfaction threshold, with the majority of ACT online participants scoring above the middle point on satisfaction ratings. Secondly, further investigation would be deemed feasible if effect sizes following online ACT for key outcomes, including functioning and mood, and treatment processes, such as pain acceptance, were at least small compared to the control condition.

Data Analysis

Independent samples t-tests, Mann-Whitney U tests, and Chi-square tests

were conducted as appropriate to compare the ACT online and control conditions on baseline variables, ACT online treatment completers and non-completers, and participants who did and did not complete follow-up assessments. A content analysis was conducted for responses to open-ended satisfaction questions. For secondary outcomes, our intention was to estimate between condition effect sizes. Since this was a feasibility study, it was not powered to detect potential treatment effects so significance testing was not undertaken. For continuous secondary outcomes, intention-to-treat linear mixed effects regression models with maximum likelihood estimation were used (accounting for data missing at random). These random intercept mixed models included treatment group, time, treatment group by time interaction, and the baseline score for the outcome being evaluated as fixed effects. For secondary outcome data that included counts (healthcare and medication use), mixed poisson generalised estimating equations were conducted using a similar approach as described above. Given this was a feasibility study, a full sensitivity analysis testing various missing data assumptions was not viable. However, we re-ran the analyses using a conservative last observation carried forward imputation approach. Standard deviations were computed from estimated model standard errors. Effect sizes of 0.20, 0.50, and 0.80 were considered to be small, medium, and large, respectively (Cohen 1988).

Results

Primary Feasibility Outcomes

Recruitment

Of the 139 potential participants referred to the study, 87 were interested and eligible (62.6%; 95% Confidence Interval (CI): 54.0-70.6%). Of these, 70 (80.5%; 95% CI: 70.6-88.2%) provided consent, indicating their willingness to be randomized. Seven participants did not complete baseline questionnaires following consent, and were not randomized. The final baseline sample of 63 participants represents a recruitment rate of 45.3% (95% CI: 36.9- 54.0%) of total study referrals during a period of 11 months. Thirty-one participants were randomised to ACT online and 32 to the control. The groups did not significantly differ on any baseline demographic or study variable (Table 1).

ACT online treatment completion

One participant did not begin the online treatment as they could not be contacted. Of the 31 participants randomized to ACT online, nineteen (61.3%; 95% CI: 42.2-78.1%) completed at least 7 out of 10 treatment sessions, and were regarded as 'treatment completers'. Thirteen (41.9%; 95% CI: 24.5-60.9%) participants completed all treatment sessions. On average, participants completed 6.90 (sd=3.49) sessions. The following were reasons for partial completion: lack of time (n=3); other health issues (n=2); computer broke (n=1); sickness/death in family (n=2); treatment unhelpful (n=1); wants pain reduction only (n=1); unknown (n=1). No serious adverse events were reported to therapists.

Employment status was significantly different between treatment completers and non-completers: Only 44% of participants engaged in any form of work (full-time, part-time, volunteering, caregiving, homemaking, or studying) completed treatment, whereas 80% of those not working completed treatment, $\chi^2=4.29$, $p=0.04$. Treatment completers and non-completers did not differ significantly on any other variable at

baseline (i.e., age, gender, living status, education, pain duration and location, receipt of disability benefits, litigation status, pain intensity or distress, disability, mood, medication or healthcare use, or psychological flexibility processes).

Study retention and data completeness

Forty-eight participants completed the three-month assessment (76.2%; 95% CI: 63.8-86.0%), while 49 participants completed the nine-month follow-up (77.8%; 95% CI: 65.5-87.3%). No data were missing from baseline assessment questionnaires. Only one item was missing from one questionnaire at three months. At nine months, four items on both the WSAS and CPAQ-8, and the PGIC item were not completed and, therefore, data on these questionnaires were not included for one participant in the nine-month analyses.

Participants who completed the nine-month follow-up reported a higher mean rank of baseline medications, as compared to those who did not complete this assessment, $U=166.00$, $p = 0.003$. The mean rank for number of medications for participants who completed the three-month assessment approached being significantly higher than participants who did not complete this assessment, $U=252.00$, $p=0.07$. Participants who provided three- and nine-month assessment data did not differ significantly from those who did not complete these assessments on any other study variables.

Treatment Satisfaction

Participants' scores on treatment satisfaction items were non-normally distributed. Therefore, median scores and ranges are reported. The median treatment satisfaction score for ACT online was 38 (range: 10-47) out of a possible

score of 50. The median satisfaction score of participants in the control condition was 31 (range: 0-46), $U=184.00$, $p<0.05$. The majority (65.2-91.3%) of ACT online participants scored five or above on all five general treatment satisfaction items. In contrast, 40.0-76.0% of participants in the control condition scored five or above on the satisfaction items.

The majority (69.6-91.3%) of ACT online participants rated the helpfulness of all ACT-specific treatment items as five or above. Analysis of open-ended satisfaction questions indicated the most frequently reported benefit was 'learning new tools to manage difficult thoughts and emotions', and 'gaining a different perspective on the pain problem'. Feeling cared for or understood was also a frequently reported helpful component, as was the flexibility of treatment delivery. The most frequently reported 'negative effect' was that treatment brought up difficult thoughts and feelings. The most common suggested improvements were to simplify the videos and to provide printed materials alongside the online treatment.

Secondary Feasibility Outcomes

Estimates of treatment effect at three and nine month follow-ups

The majority of ACT online participants reported being much improved or very much improved on the PGIC at the three-month follow-up (56.5%) compared to only 20.0% in the control condition (Odds Ratio=5.20, 95% CI: 1.45-18.71). However, only 27.3% of ACT online participants reported being much improved or better at nine months compared to 15.4% in the control group (Odds Ratio=2.06, 95% CI: 0.50-8.53).

Differences with less than small effects between groups were observed for pain intensity and distress at both follow-ups (Table 2). For pain interference (BPI)

and functioning (WSAS), small effect size improvements in favour of ACT online were observed at three months; these increased to medium effects at nine months. ACT online showed a medium effect size improvement in depression over control participants at three-months; however, the difference between groups at nine months was less than a small effect. Small effect size improvements favouring ACT online participants were observed for medication and healthcare use at three months; however, this improvement was only maintained for healthcare use at nine months.

For treatment process variables, the between groups effect sizes at three months were small for committed action and decentering, and large for pain acceptance. However, at nine months the difference between groups on decentering and pain acceptance was less than a small effect. A small effect size favouring ACT online participant was maintained at nine months for committed action.

Effect sizes were mostly consistent using the more conservative last observation carried forward (LOCF) imputation approach, with a few exceptions. Using LOCF, the effect for pain acceptance reduced from large to medium at three months. Effects reduced from medium to small for depression at three months, and BPI pain interference and WSAS at nine months. The effect for committed action at nine months reduced from small to less than small. Lastly, the effect for healthcare visits at three months *increased* from small to medium.

Discussion and Conclusions

The purpose of this study was to determine the feasibility of online ACT and a larger trial testing its efficacy for patients with chronic pain and clinically-meaningful disability and distress presenting at a speciality pain clinic in the United Kingdom. The absolute number of participants recruited was less than planned, and our

treatment completion rate (61%) was less than anticipated (70%). However, the recruitment rate relative to referrals (45%) is higher than two previous RCTs of online ACT for pain in Sweden and Germany (Buhrman et al., 2013; Lin et al., 2017). Moreover, our follow-up retention (76-78%) is consistent with a larger Dutch trial (Trompetter et al., 2014). Effect sizes at three months ranged from small to large favouring ACT online for functioning, mood, medication and healthcare use. Although effects for mood and medication use at nine months were less than small, small to medium effects were maintained for functioning and healthcare use. Taken together, the data provide support for the feasibility of online ACT in this context and for a larger efficacy trial, following some adjustments to treatment delivery and trial procedures. Notably, baseline pain intensity, disability, and depression were more severe in our sample compared to previous online ACT studies using community samples (Lin et al., 2017; Trompetter et al., 2014). Thus, the current study provides evidence for the generalizability of online ACT across contexts.

Recruitment in our trial may have been hampered by the use of a treatment as usual control group. We deemed this control group acceptable for feasibility purposes given limited knowledge about the efficacy of other active online psychological treatments in our context, and limited resources for providing therapist support for control participants subsequent to their study completion. However, use of a waitlist control condition in a larger trial may increase participation.

The ACT online treatment completion rate observed (61%) was similar to that in the German trial of online ACT (60%), but lower than the Dutch trial (72%) (Trompetter et al., 2014). Employment status was the only variable that differed between treatment completers and non-completers, such that employed participants were significantly less likely to complete ACT online. Thus, treatment could more

explicitly address practical (e.g., time) and psychological (e.g., work-related stress) barriers to completion for employed participants in the early sessions. A subsequent delivery system that better tailors the content and sequence of sessions to the specific needs of individual patients may likewise increase treatment engagement. Practical refinements recommended by participants in our trial, such as shortening the videos and providing printed materials, may also enhance engagement. Future research, perhaps including in-depth interviews, with treatment non-completers may help to further elucidate the reasons for not engaging in online ACT to inform further developments of the treatment.

Less than small effects between groups were observed for pain intensity and distress, which is unsurprising in light of the aim of ACT to improve functioning and quality of life, rather than to reduce pain (Hann and McCracken 2014; Veehof et al., 2016). Previous research suggests that patients' overall impression of change following treatment for pain is influenced to a greater degree by improvements in daily functioning and mood than changes in pain intensity (Scott and McCracken 2015a). The capacity of ACT online to address functioning and mood likely contributed to higher rates of improvement on the PGIC in this group compared to the control group, which received treatment principally focussed on pain reduction.

Effects favouring online ACT at the three-month assessment were small for decentering, and committed action, and large for pain acceptance. Although there were less than small effects for decentering and acceptance at nine months, the effect for committed action was maintained at this assessment. The study by Trompetter et al. (2014) reported medium effects at post-treatment and follow-up for psychological flexibility. Differences in measures between studies may account for these discrepancies. In a non-randomized study of patients receiving intensive

interdisciplinary ACT for chronic pain, the pre- to post-treatment effects for acceptance, decentering, and committed action were comparable to the between-groups effects observed on these variables in the current study (Scott et al., 2016).

The outcome estimates reported here may be used to perform sample size calculations for a larger trial. Using our three-month WSAS estimates, for 80% power and $p < 0.05$, a two arm trial using a treatment as usual or waitlist control should have 80 participants per group post-treatment. Of course, an active psychological treatment is needed to definitively test the efficacy for the current version of online ACT. It is unlikely that online ACT will be found to be superior to online CBT (Veehof et al., 2016). Therefore, a more useful strategy for a future trial would be to compare face-to-face and online ACT. A recent non-inferiority trial compared ACT delivered via video conferencing (using more intensive therapist support than the current study), to in-person delivery in United States veterans (Herbert et al., 2017). Support for non-inferiority of remote delivery was found; however, there was greater attrition in the teleconferencing arm (Herbert et al., 2017). This further illustrates the importance of optimising engagement of remotely delivered ACT.

This study must be considered in light of several limitations. Participants and therapists were not blinded to condition, outcome measures were based on self-report, and the sample was relatively small. Therefore, effect sizes may be overestimated. Future research with a larger sample would benefit from using more frequent sampling methods, such as ecological momentary assessment (Shiffman et al., 2008), and objective indicators of functioning, including actigraphy (e.g., Wadley et al., 2016). We did not collect data on specific pain diagnoses or aetiology. Future research should investigate Internet-delivered ACT in specific pain conditions, such as neuropathic pain, particularly given the dearth of RCTs of psychological

treatments in neuropathic pain (Eccleston et al., 2014). To assess medication use, we summed the number of classes of analgesics used, which limits our understanding of important changes in medication doses. More sensitive measures of medication use and dosages would be useful in a future trial. Our trial was undertaken at one site. However, the use of therapists with a wide range of experience and the recruitment of a sample with a range of ages, pain duration, and pain locations, may reflect more general applicability. Although assessment of the Work and Social Adjustment Scale and medication use questions were included in the approved protocol, these were not specified during our trial registration.

Despite these limitations, this is the first study to support the feasibility of online ACT in participants with complex chronic pain in the United Kingdom. Data from this trial can be used to inform further ACT online treatment development. Ultimately, this research may improve treatment access and patient outcomes.

Trial Registration: The trial was registered prior to recruitment of the first participant and a summary protocol is available online (ISRCTN81739991).

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data. BG and ADE contributed to the acquisition and interpretation of data. LM contributed to the conception and design of the study, as well as the acquisition and interpretation of the data. All authors contributed to drafting and revising of the article. All authors approved the final version.

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Figure 1. CONSORT Flow Diagram

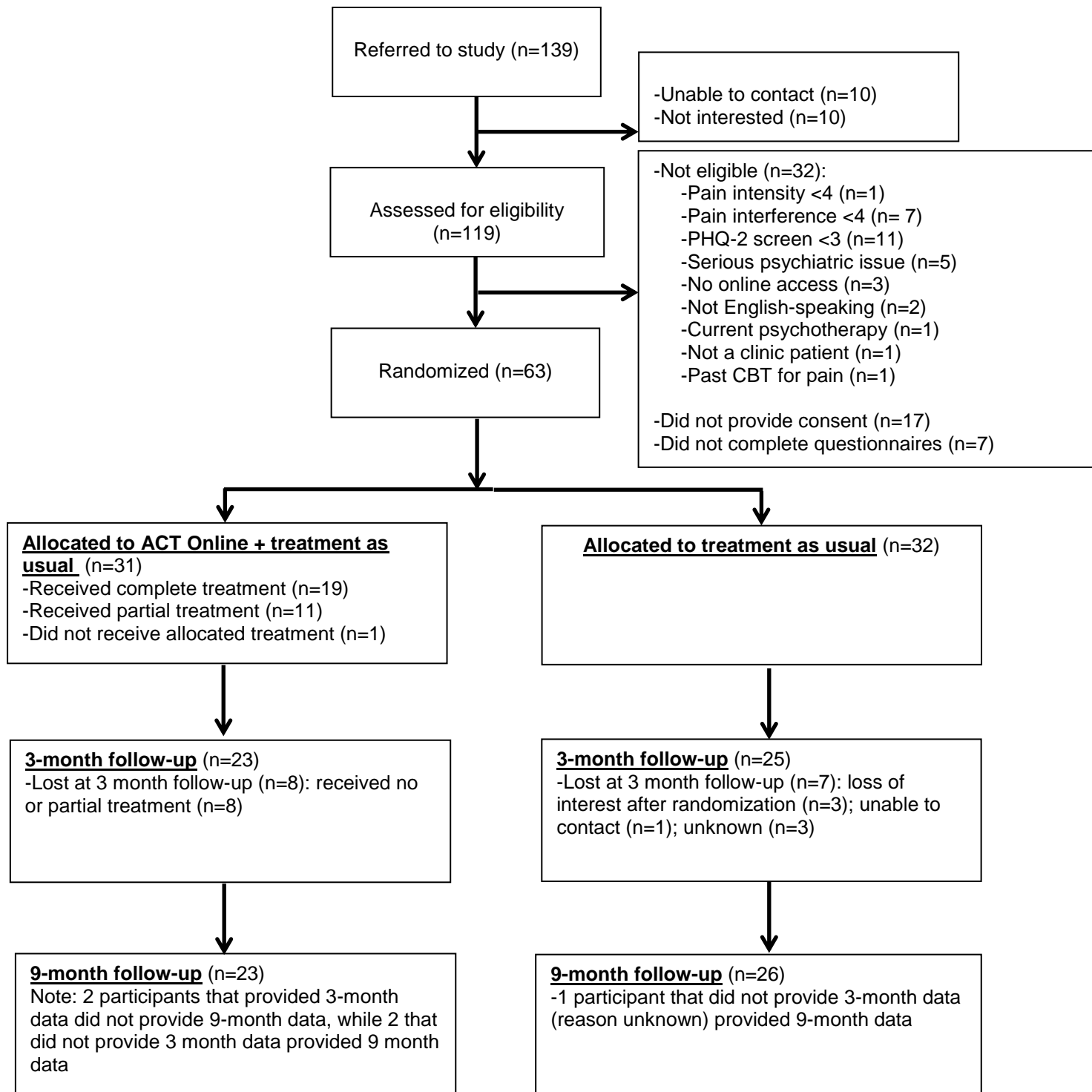


Table 1. Baseline comparison between groups on demographic and study variables.

		ACT Online Mean (SD) or <i>n</i> (%)	Control Mean (SD) or <i>n</i> (%)	Between-groups comparison
Gender	Women	21 (67.7)	19 (59.4)	$\chi^2=0.48$, $p=0.49$
	Men	10 (32.3)	13 (40.6)	
Age (years)		47.26 (14.00)	43.84 (13.97)	$t=-0.97$, $p=0.34$
Ethnicity	White	24 (77.4)	27 (84.4)	$\chi^2=0.49$, $p=0.48$ †
	Black	4 (12.9)	1 (3.1)	
	Asian	2 (6.5)	1 (3.1)	
	Mixed/Other	1 (3.2)	3 (9.4)	
Living status	Alone	2 (6.5)	8 (25.0)	Fisher's, $p=0.08$ ^b
	With partner	11 (35.5)	9 (28.3)	
	With children	4 (12.9)	2 (6.3)	
	With partner and children	11 (35.5)	5 (15.6)	
	Other relatives	2 (6.5)	2 (6.3)	
	With friends/flatmates	1 (3.2)	6 (18.8)	
Years of education		14.5 (10-20) ^a	15 (10-21) ^a	$U=368.50$, $p=0.08$
Work status	Employed full time	8 (25.8)	11 (34.4)	$\chi^2=0.43$, $p=0.51$ ^b
	Employed part time due to pain	6 (19.4)	5 (15.6)	
	Employed part time--other	0 (0.0)	5 (15.6)	
	Unpaid volunteer	1 (3.2)	0 (0.0)	
	Homemaker	1 (3.2)	0 (0.0)	
	Unemployed because of pain	7 (22.6)	6 (18.8)	
	Unemployed for other reason	2 (6.5)	1 (3.1)	
	Student	1 (3.2)	0 (0.0)	
	Retired	5 (16.1)	4 (12.5)	
Disability income		15 (48.4)	10 (31.3)	$\chi^2=1.93$, $p=0.17$
Legal action related to pain	Current	1 (3.2)	3 (9.4)	Fisher's, $p=0.61$
	Past	4 (12.9)	3 (9.4)	Fisher's, $p=0.71$
Pain Duration (years)		7.25 (1.75-47.50) ^a	5.63 (0.75-29.75) ^a	$U=424.00$, $p=0.32$
Primary pain location	Head, face or mouth	1 (3.2)	5 (15.6)	$\chi^2=0.82$, $p=0.37$ ^b
	Neck region	4 (12.9)	2 (6.3)	
	Upper shoulder/limbs	1 (3.2)	4 (12.5)	
	Chest region	1 (3.2)	0 (0.0)	
	Lower back/spine	11 (35.5)	8 (25.0)	
	Lower limbs	3 (9.7)	5 (15.6)	
	Pelvic region	3 (9.7)	4 (12.5)	
	Anal/genital	1 (3.2)	1 (3.1)	
	Widespread pain	6 (19.4)	3 (9.4)	
Medication Classes		2.77 (1.65)	2.84 (1.42)	$t=0.18$, $p=0.86$
Average Pain Intensity		7.52 (1.34)	7.31 (1.20)	$t=-0.64$, $p=0.53$
Average Pain Distress		7.39 (1.91)	7.22 (1.84)	$t=-0.36$, $p=0.72$
Brief Pain Inventory—Interference Scale		7.71 (1.54)	6.95 (1.66)	$t=-1.89$, $p=0.06$
Disability (Work and Social Adjustment Scale)		30.32 (8.26)	26.69 (8.72)	$t=-1.70$, $p=0.10$
Depression		14.19 (6.16)	13.19 (5.31)	$t=-0.70$, $p=0.49$
Healthcare Visits		4.00 (0-29) ^a	3.00 (1-17) ^a	$U=381.00$, $p=0.42$
Pain Acceptance		23.26 (7.49)	22.03 (7.02)	$t=-0.67$, $p=0.51$
Decentering		36.35 (5.59)	36.66 (6.76)	$t=0.19$, $p=0.85$
Committed Action		34.00 (6.32)	33.06 (7.90)	$t=0.52$, $p=0.61$

Note: ^a Median and range; ^b Due to multiple categories and small numbers per cell, variables were re-coded to have two categories for the between group comparison: white/minority; employed/unemployed; living with other people/living alone; back pain/other pain.

Table 2. Comparisons between groups on three- and nine-month assessment variables.

Outcome	Adjusted Means ^a (95% confidence intervals)			LOCF Adjusted Means ^b (95% confidence intervals)		
	Online ACT	Control	Effect size (d)	Online ACT	Control	Effect size (d)
Average Pain						
3-month	6.3 (5.5, 7.1)	5.9 (5.0, 6.8)	0.19	6.5 (5.9, 7.2)	6.2 (5.5, 6.9)	0.16
9-month	6.1 (5.3, 7.0)	5.9 (5.1, 6.8)	0.10	6.4 (5.7, 7.0)	6.2 (5.5, 6.9)	0.11
Average Distress						
3-month	5.5 (4.7, 6.4)	5.4 (4.6, 6.1)	0.05	5.7 (5.0, 6.5)	5.6 (4.9, 6.2)	0.06
9-month	5.5 (4.7, 6.4)	5.5 (4.8, 6.3)	0.01	5.6 (4.9, 6.3)	5.6 (5.0, 6.3)	0.01
BPI Pain Interference						
3-month	5.7 (5.0, 6.3)	6.1 (5.4, 6.7)	0.24	5.9 (5.4, 6.5)	6.2 (5.7, 6.7)	0.20
9-month	5.4 (4.8, 6.1)	6.3 (5.7, 7.0)	0.54	5.8 (5.3, 6.4)	6.4 (5.9, 6.9)	0.40
Disability (WSAS)						
3-month	20.2 (17.2, 23.2)	23.4 (20.5, 26.2)	0.45	22.0 (19.7, 24.4)	23.8 (21.5, 26.1)	0.27
9-month	20.0 (17.0, 23.0)	23.7 (20.9, 26.5)	0.50	21.3 (18.9, 23.6)	24.1 (21.8, 26.4)	0.42
Depression						
3-month	10.0 (8.3, 11.6)	12.1 (10.4, 13.7)	0.51	10.7 (9.3, 12.0)	12.4 (11.0, 13.8)	0.44
9-month	11.6 (9.9, 13.3)	12.0 (10.4, 13.7)	0.14	11.7 (10.4, 13.1)	12.3 (10.9, 13.6)	0.16
Medication Use						
3-month	2.0 (1.6, 2.5)	2.3 (1.9, 2.7)	0.27	2.0 (1.7, 2.5)	2.3 (1.9, 2.7)	0.27
9-month	2.0 (1.6, 2.4)	1.9 (1.5, 2.4)	0.10	2.0 (1.7, 2.5)	1.9 (1.5, 2.3)	0.10
Healthcare Visits						
3-month	4.0 (2.9, 5.4)	4.7 (3.5, 6.3)	0.20	4.2 (3.2, 5.3)	4.8 (4.0, 5.9)	0.50
9-month	3.6 (2.7, 4.9)	5.1 (3.4, 7.7)	0.35	3.7 (3.0, 4.7)	5.1 (3.9, 6.7)	0.40
Pain Acceptance						
3-month	28.4 (26.7, 30.0)	24.8 (23.3, 26.4)	0.87	27.1 (25.7, 28.5)	24.5 (23.1, 25.9)	0.69
9-month	26.8 (25.1, 28.5)	26.6 (25.1, 28.1)	0.05	25.5 (24.1, 26.9)	26.0 (24.6, 27.4)	0.13
Decentering						
3-month	39.4 (37.1, 41.7)	37.0 (34.7, 39.2)	0.42	38.9 (37.1, 40.8)	36.7 (34.9, 38.4)	0.42
9-month	38.7 (36.4, 41.0)	38.2 (36.0, 40.4)	0.10	38.4 (36.5, 40.3)	37.8 (36.0, 39.5)	0.12
Committed Action						
3-month	33.6 (31.6, 35.7)	32.4 (30.4, 34.4)	0.26	34.0 (32.3, 35.8)	32.8 (31.2, 34.5)	0.25
9-month	35.4 (33.3, 37.5)	33.3 (31.3, 35.2)	0.42	34.1 (32.4, 35.9)	33.7 (32.1, 35.4)	0.10

Note: ^aSample sizes (online ACT vs control) for baseline, 3- and 9-months were 31 vs. 32, 23 vs. 25, and 23 vs. 26, respectively.

^bLast observation carried forward (LOCF) imputed model. Sample sizes 31 (online ACT) vs. 32 (Control) at each time point.

Between condition effect size= Cohen's d.

All models adjusted for the baseline value of the corresponding outcome.

Table S1. Summary of treatment sessions

Session number and title	Processes	Metaphors and Exercises
1. Therapist contact: face-to-face or by telephone	Creative hopelessness; exploring what matters	Review of the pain problem; strategies to manage pain and short- and long-term results of these; finger trap exercise; treatment goals
2. Online session 1: The struggle with pain	Treatment overview; Creative hopelessness	Setting expectations for treatment; Passengers on the bus metaphor
3. Online session 2: Building openness	Openness	Introduction to “open, aware, and engaged”; Your unwanted party guest; connect, breath, and open up exercise
4. Online session 3: Opening up to thoughts	Cognitive Defusion	The problem with controlling thoughts (“do not think of...” exercise); having a thought and doing the opposite; labelling thoughts exercise
5. Online session 4: Connecting with your values	Values-based action	Choosing your focus exercise; the difference between goals and values; 80 th birthday exercise; values assessment rating form
6. Online session 5: Flexible present-focussed awareness	Awareness and openness	Tracking thoughts in time exercise; Notice 5 things exercise
7. Online session 6: Building committed action	Committed action	The swamp metaphor; Small steps exercise; goal-setting worksheet
8. Online session 7: The observer self	Self-as-Context	Self-as-observer exercise; Sky versus weather metaphor
9. Online session 8: Putting it all together	Self-as-context; committed action	Brief self-as-observer exercise; setting longer-term goals; goal-setting worksheet
10. Final therapist contact: face-to-face or by telephone	Reviewing progress and maintaining gains	Review of skills and summary of changes in diary items during treatment; review goals for coming months; identify and plan for barriers